



**BILLING CODE 6560-50-P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

**[EPA-HQ-OPP-2012-0493; FRL-9361-4]**

**Sulfoxaflor; Pesticide Tolerances for Emergency Exemptions**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes time-limited tolerances for residues of sulfoxaflor, N-methyloxido [1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]  $\lambda^4$ -sulfanylidene] cyanamide, including its metabolites and degradates in or on cotton, undelinted seed; cotton, gin byproducts; and cotton, hulls. This action is in response to EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on cotton. This regulation establishes maximum permissible levels for residues of sulfoxaflor in or on these commodities. These time-limited tolerances expire on December 31, 2015.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

**SUPPLEMENTARY INFORMATION.**

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0493, is available at <http://www.regulations.gov> or at the

OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001.

The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Libby Pemberton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: 703-308-9364; email address: [pemberton.libby@epa.gov](mailto:pemberton.libby@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0493 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0493, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

## **II. Background and Statutory Findings**

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of sulfoxaflor, N-methyloxido [1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]  $\lambda^4$ -sulfanylidene] cyanamide, including its metabolites and degradates in or on cotton, undelinted seed at 0.2 parts per million (ppm); cotton, gin byproducts at 6.0 ppm; and cotton, hulls at 0.35 ppm. These time-limited tolerances expire on December 31, 2015.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA

section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### **III. Emergency Exemption for Sulfoxaflor for Various Commodities and FFDCA Tolerances**

The states of Arkansas, Mississippi, Tennessee, and Louisiana submitted emergency use requests for the use of the unregistered active ingredient, sulfoxaflor, on cotton to control the tarnished plant bug. The requests are a result of the resurgence of tarnished plant bug as a primary pest of cotton. The states assert growers are facing a longer control season for tarnished plant bug. In addition, tarnished plant bug has developed resistance to registered alternatives. After having reviewed the submissions, EPA determined that emergency conditions exist for these States, and that the criteria for emergency exemptions are met. EPA has authorized specific exemptions under FIFRA section 18 for the use of sulfoxaflor on cotton for control of tarnished plant bug in Arkansas, Mississippi, Tennessee, and Louisiana.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of sulfoxaflor in or on cotton. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2015, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on cotton, undelinted seed; cotton, ginbyproducts; and cotton, hulls after that date

will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether sulfoxaflor meets FIFRA's registration requirements for use on cotton or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerances decision serves as a basis for registration of sulfoxaflor by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Arkansas, Mississippi, Tennessee, and Louisiana to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for sulfoxaflor, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for

which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .”

Consistent with the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure expected as a result of these emergency exemption requests and the time-limited tolerances for combined residues of sulfoxaflor in or on cotton, undelinted seed at 0.2 parts per million (ppm); cotton, gin byproducts at 6.0 ppm; and cotton, hulls at 0.35 ppm. Use of cotton commodities conforming to these temporary tolerances as animal feed is not expected to produce sulfoxaflor residues in livestock commodities. EPA's assessment of exposures and risks associated with establishing these time-limited tolerances follows.

#### *A. Toxicological Points of Departure/Levels of Concern*

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which



no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect during a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see

<http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for sulfoxaflor used for human risk assessment is shown in the Table of this unit.

**Table —Summary of Toxicological Doses and Endpoints for Sulfoxaflor for Use in Human Health Risk Assessment**

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13-50 years of age)	NOAEL = 1.8 mg/kg/day  UF <sub>A</sub> = 3x  UF <sub>H</sub> = 10x	Acute RfD = 0.06 g/kg/day  aPAD = 0.06 mg/kg/day	Developmental Neurotoxicity Study  LOAEL = 7.1 mg/kg/day based on decreased neonatal

	FQPA SF = 1x		survival on postnatal day 0 through 4
Acute dietary (General population including infants and children)	NOAEL = 25 mg/kg/day  UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Acute RfD =0.25 mg/kg/day  aPAD = 0.25 mg/kg/day	Acute Neurotoxicity Study  LOAEL = 75 mg/kg/day based on decreased motor activity.
Chronic dietary (All populations)	NOAEL= 5.13 mg/kg/day  UF <sub>A</sub> = 10x UF <sub>H</sub> = 10x FQPA SF = 1x	Chronic RfD = 0.05 mg/kg/day  cPAD = 0.05 mg/kg/day	Chronic/Carcinogenicity Study in the Rat  LOAEL = 21.3 mg/kg/day based on liver effects including increased blood cholesterol, liver weight, hypertrophy, fatty change, single cell necrosis and macrophages observed in the males and females.
Cancer (Oral, dermal,	Sulfoxaflo is classified as “Suggestive Evidence of Carcinogenic		

inhalation)	Potential.” Quantification of risk using a non-linear approach (i.e., RfD) will adequately account for all chronic toxicity, including carcinogenicity.
-------------	---

UF<sub>A</sub> = extrapolation from animal to human (interspecies). UF<sub>H</sub> = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. LOAEL = lowest observed adverse effect level. NOAEL = no observed adverse effect level.

### *B. Exposure Assessment*

1. Dietary exposure from food and feed uses. In evaluating dietary exposure to sulfoxaflor, EPA considered exposure under the time-limited tolerances established by this action. EPA assessed dietary exposures from sulfoxaflor in food as follows:

i. *Acute and Chronic exposure.* Acute and chronic effects were identified for sulfoxaflor. In estimating acute and chronic dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). EPA’s dietary exposure assessment assumed that all cotton in the U.S. is treated with sulfoxaflor (i.e., 100% crop treated); an empirical factor of 0.1X to account for the reduction in sulfoxaflor residues during the processing of cottonseed into oil (which is the only human food associated with cotton); and used health-protective models to estimate residues in drinking water.

ii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk may be quantified using a linear

or nonlinear approach. If sufficient information is available to determine the carcinogenic mode of action, and that mode of action has a threshold, then EPA will use a threshold or nonlinear approach and calculate a cancer RfD based on an earlier noncancer key event. If the mode of carcinogenic action is unknown, or if the mode of action appears to be mutagenic, a default linear cancer slope factor approach is utilized. Based on studies demonstrating key events of a hypothesized mode of action leading to the observed tumors and no mutagenicity concerns, EPA has concluded that a nonlinear RfD approach is appropriate for assessing cancer risk to sulfoxaflor. Cancer risk was assessed using the same exposure estimates as discussed in Unit IV.B.1.i., acute and *chronic exposure*.

iii. *Anticipated residue and percent crop treated (PCT) information*. EPA did not use anticipated residue and/or PCT information in the dietary assessment for sulfoxaflor. For this risk assessment, EPA assumed that all cottonseed oil contains tolerance level residues (modified by an empirical processing factor) and that 100% of cotton is treated with sulfoxaflor.

2. *Dietary exposure from drinking water*. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for sulfoxaflor in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of sulfoxaflor. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model /Exposure Analysis Modeling System (PRZM/EXAMS) and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of sulfoxaflor for acute exposures

are estimated to be 2.76 parts per billion (ppb) for surface water and 45.1 ppb for ground water; for chronic exposures for non-cancer assessments are estimated to be 0.865 ppb for surface water and 45.1 ppb for ground water. Environmental fate data indicate that the predominant residue in surface water will be the parent compound and the predominant residue in groundwater will be the X11719474 metabolite (88% of the total residue) and X11519450 (12% of the total residue). For convenience, EPA's exposure assessment multiplies the relative toxicity of each metabolite by its proportion to express the residue concentration in terms of parent sulfoxaflor-equivalents.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 0.045 ppm (0.0397 ppm X11719474 + 0.0054 ppm X11519450) was used to assess the contribution of drinking water to dietary exposure for the general population, except women of child-bearing age (13-49 years). For females 13-49 years old, the acute surface water EDWC (0.0028 ppm) was used to assess the contribution of drinking water. For chronic dietary risk assessment for the general population, including females 13-49 years old, the ground water concentration of value 0.066 ppm was used to assess the contribution of drinking water. The groundwater value of 0.066 ppm reflects individual concentrations of X11719474 and X11519540, adjusted for their relative potencies of 0.3X and 10X, respectively.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Sulfoxaflor is currently not registered for any use that will result in residential exposure.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at:

<http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.*

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide's residues and“ other substances that have a common mechanism of toxicity.”

EPA has not found sulfoxaflor to share a common mechanism of toxicity with any other substances, and sulfoxaflor does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that sulfoxaflor does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

*C. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA

either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicity databases for sulfoxaflor are complete. Although adverse developmental effects were observed in rats, the mode of action is understood and does not appear relevant to humans. Data indicate that juvenile rats are uniquely sensitive to perturbation of the muscular nicotinic receptor by sulfoxaflor, leading to sustained muscle contraction and increased neonatal deaths. Supporting studies indicate that sulfoxaflor does not interact with nicotinic receptors in the adult rat, fetal human, or adult human. Furthermore, the observation that no neonatal deaths or neuromuscular/skeletal effects were noted in the rabbit developmental toxicity study supports the conclusion that rats are uniquely sensitive to developmental toxicity due to sulfoxaflor exposure. These differences suggest that to the extent that neonatal death in rats occurs as a result of sulfoxaflor binding to the fetal receptor, these effects would not be observed in humans.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings: the level of concern for neurotoxicity is low because the effects are well characterized and clear NOAELs are established. Similarly, although there is increased quantitative susceptibility in the developmental neurotoxicity (DNT) study, the level of concern for the increased susceptibility is low because the effects are well characterized and the endpoints chosen for risk assessment are protective of potential *in utero* developmental effects. In addition, the exposure assessments are highly conservative and unlikely to underestimate exposure/risk.

#### *D. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to sulfoxaflor will occupy 4% of the aPAD for infants (<1 year), the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to sulfoxaflor from food and water will utilize 9% of the cPAD for infants (<1 year) the population group receiving the greatest exposure. There are no residential uses for sulfoxaflor.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). A short-term adverse effect was identified; however, sulfoxaflor is not registered for any use patterns that would result in short-term residential exposure. Because there is no short-term residential exposure, sulfoxaflor poses no short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level).



An intermediate-term adverse effect was identified; however, sulfoxaflor is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure, sulfoxaflor poses no intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* EPA determined that there is a “Suggestive Evidence of Carcinogenic Potential” for sulfoxaflor based on the preputial gland tumor response seen in rats. When there is suggestive evidence, the Agency does not attempt a dose-response assessment as the nature of the data generally would not support one. Rather, the Agency has determined that quantification of risk using a non-linear approach (i.e., reference dose (RfD)) will adequately account for all chronic toxicity, including carcinogenicity, that could result from exposure to sulfoxaflor.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to sulfoxaflor residues.

## **V. Other Considerations**

### *A. Analytical Enforcement Methodology*

Adequate analytical methods have been submitted for both data collection and for enforcement purposes. In the submitted field trial and processing studies, residues of sulfoxaflor and its metabolites in crops were determined using 2 different Dow analytical methods (designated as 091031 or 091116). The proposed method for tolerance enforcement in plant commodities is method 091116: Enforcement Method for the Determination of Sulfoxaflor (XDE-208) and its Main Metabolites in Agricultural

Commodities using Offline Solid-Phase Extraction and Liquid Chromatography with Tandem Mass Spectrometry Detection. Method 091116 extracts residues with acetonitrile/water and includes use of a deuterated internal standard, hydrolysis with NaOH to release base-labile conjugates, and clean up via solid-phase extraction. This method is applicable for the quantitative determination of residues of sulfoxaflor and its metabolites in agricultural commodities and processed products. The method was adequately validated, with a limit of quantitation (LOQ) of 0.010 mg/kg for all matrices. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

#### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for sulfoxaflor.

## **VI. Conclusion**

Therefore, time-limited tolerances are established for residues of, sulfoxaflor, N-methyloxido [1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]  $\lambda^4$ -sulfanylidene] cyanamide including its metabolites and degradates, in or on cotton, undelinted seed at 0.2 parts per million (ppm); cotton, ginbyproducts at 6.0 ppm; and cotton, hulls at 0.35 ppm. These tolerances expire on December 31, 2015.

## **VII. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

### **VIII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA

will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

#### **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 20, 2012.

Steven Bradbury,

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.668 is added to subpart C to read as follows:

**§ 180.668 Sulfoxaflor; tolerances for residues.**

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the insecticide, sulfoxaflor, N-methyloxido [1-[6-(trifluoromethyl)-3-pyridinyl]ethyl]  $\lambda^4$ -sulfanylidene] cyanamide, including its metabolites and degradates, in or on the commodities in the following table resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions.

Compliance with the tolerance levels specified in the following table is to be determined by measuring only sulfoxaflor in or on the commodity. The tolerances expire on the date specified in the table.

Commodity	Parts per million	Expiration date
Cotton, undelinted seed	0.2	12/31/15
Cotton, gin byproducts	6.0	12/31/15
Cotton, hulls	0.35	12/31/15

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 2012-23818 Filed 09/27/2012 at 8:45 am; Publication Date: 09/28/2012]